

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF TENNESSEE
NORTHEASTERN DIVISION

DENNIS O'BRIEN, and wife,
KAYE O'BRIEN,

Plaintiffs,

v.

NEW ENGLAND COMPOUNDING
PHARMACY INC. aka NEW ENGLAND
COMPOUNDING CENTER (NECC);
MEDICAL SALES MANAGEMENT, INC;
AMERIDOSE, LLC;
GREGORY CONIGLIARO, individually
and d/b/a the above named business
organizations;
BARRY CADDEN, , individually and d/b/a
the above named business organizations; and
LISA CADDEN, , individually and d/b/a the
above named business organizations;
CARLA CONIGLIARO, , individually and
d/b/a the above named business
organizations; and
DOUGLAS CONIGLIARO, , individually
and d/b/a the above named business
organizations;

Defendants.

CASE NO. 2:12-cv-00117

JUDGE: KEVIN H. SHARP

DEFENDANT AMERIDOSE, LLC'S
ANSWER AND AFFIRMATIVE
DEFENSES TO PLAINTIFFS'
COMPLAINT

Defendant Ameridose, LLC, by and through its undersigned counsel, hereby answers
Plaintiffs' Complaint as follows:

PARTIES

1. Defendant lacks knowledge or information sufficient to form a belief about the
truth of the allegations in Paragraph 1.

2. The allegations in Paragraph 2 are not directed to this Defendant so no response is
required. To the extent one is deemed required, Defendant denies the allegations in Paragraph 2

for lack of knowledge or information sufficient to form a belief about the truth of these allegations.

3. The allegations in Paragraph 3 are not directed to this Defendant so no response is required. To the extent one is deemed required, Defendant denies the allegations in Paragraph 3 for lack of knowledge or information sufficient to form a belief about the truth of these allegations.

4. The allegations in Paragraph 4 are not directed to this Defendant so no response is required. To the extent one is deemed required, Defendant denies the allegations in Paragraph 4 for lack of knowledge or information sufficient to form a belief about the truth of these allegations.

5. Defendant admits that it is a Massachusetts Limited Liability Company with a principal place of business at 205 Flanders Road, Westborough, Massachusetts 01581. Defendant further admits that its registered agent for service of process is Gregory Conigliaro.

6. Because “Manager” is undefined, Defendant denies that Gregory Conigliaro is a Manager of Ameridose. Defendant lacks knowledge or information sufficient to form a belief about the remaining allegations in Paragraph 6.

7. Because “Manager” is undefined, Defendant denies that Barry J. Cadden is a Manager of Ameridose. Defendant lacks knowledge or information sufficient to form a belief about the remaining allegations in Paragraph 7.

8. The allegations in Paragraph 8 are not directed to this Defendant so no response is required. To the extent one is deemed required, Defendant denies the allegations in Paragraph 8 for lack of knowledge or information sufficient to form a belief about the truth of these allegations.

9. The allegations in Paragraph 9 are not directed to this Defendant so no response is required. To the extent one is deemed required, Defendant denies the allegations in Paragraph 9 for lack of knowledge or information sufficient to form a belief about the truth of these allegations.

10. The allegations in Paragraph 10 are not directed to this Defendant so no response is required. To the extent one is deemed required, Defendant denies the allegations in Paragraph 10 for lack of knowledge or information sufficient to form a belief about the truth of these allegations.

FACTUAL BACKGROUND

11. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 11.

12. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 12.

13. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 13.

14. Defendant admits that it has a manufacturing license from the U.S. Food and Drug Administration. Defendant further admits that it shares certain business services with Defendant NECC. Defendant denies the remaining allegations against it in Paragraph 14 and lacks knowledge or information sufficient to form a belief about the truth of these allegations as to the other Defendants.

15. Defendant admits that Medical Sales Management provided certain shared business services to it and to Defendant NECC. Defendant denies the remaining allegations against it in Paragraph 15.

16. Defendant denies the allegations against it in Paragraph 16 and lacks knowledge or information sufficient to form a belief about the allegations as to NECC.

17. Defendant admits that its principal place of business is at 205 Flanders Road, Westborough, Massachusetts 01581.

18. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 18.

19. The allegations in Paragraph 19 are not directed to this Defendant so no response is required. To the extent one is deemed required, Defendant denies the allegations in Paragraph 19 for lack of knowledge or information sufficient to form a belief about the truth of these allegations.

20. Defendant admits that it has voluntarily suspended its operation, but denies the remaining allegations against it in Paragraph 20. Defendant lacks knowledge or information sufficient to form a belief about the allegations in Paragraph 20 as to the other Defendants.

21. The allegations in Paragraph 21 are not directed to this Defendant so no response is required. To the extent one is deemed required, Defendant denies the allegations in Paragraph 21 for lack of knowledge or information sufficient to form a belief about the truth of these allegations.

22. Defendant admits that it was originally licensed by the Tennessee Board of Pharmacy on April 23, 2010 and that it has voluntarily suspended its operation.

23. Defendant admits that it did not register with the Tennessee Secretary of State's office, but states that, by virtue of its pharmacy license, it is in substantial compliance with Tennessee law.

24. The allegations in Paragraph 24 are not directed to this Defendant so no response is required. To the extent one is deemed required, Defendant denies the allegations in Paragraph 24 for lack of knowledge or information sufficient to form a belief about the truth of these allegations.

25. The allegations in Paragraph 25 are not directed to this Defendant so no response is required. To the extent one is deemed required, Defendant denies the allegations in Paragraph 25 for lack of knowledge or information sufficient to form a belief about the truth of these allegations.

26. The allegations in Paragraph 26 are not directed to this Defendant so no response is required. To the extent one is deemed required, Defendant denies the allegations in Paragraph 26 for lack of knowledge or information sufficient to form a belief about the truth of these allegations.

27. The allegations in Paragraph 27 are not directed to this Defendant so no response is required. To the extent one is deemed required, Defendant denies the allegations in Paragraph 27 for lack of knowledge or information sufficient to form a belief about the truth of these allegations.

28. The allegations in Paragraph 28 are not directed to this Defendant so no response is required. To the extent one is deemed required, Defendant denies the allegations in Paragraph 28 for lack of knowledge or information sufficient to form a belief about the truth of these allegations.

29. The allegations in Paragraph 29 are not directed to this Defendant so no response is required. To the extent one is deemed required, Defendant denies the allegations in Paragraph

29 for lack of knowledge or information sufficient to form a belief about the truth of these allegations.

30. The allegations in Paragraph 30 are not directed to this Defendant so no response is required. To the extent one is deemed required, Defendant denies the allegations in Paragraph 30 for lack of knowledge or information sufficient to form a belief about the truth of these allegations.

31. The allegations in Paragraph 31 are not directed to this Defendant so no response is required. To the extent one is deemed required, Defendant denies the allegations in Paragraph 31 for lack of knowledge or information sufficient to form a belief about the truth of these allegations.

32. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 32.

33. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 33.

34. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 34.

35. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 35.

CAUSES OF ACTION

Strict Liability

36. The allegations in Paragraph 36 are not directed to this Defendant so no response is required. To the extent one is deemed required, Defendant denies the allegations in Paragraph

36 for lack of knowledge or information sufficient to form a belief about the truth of these allegations.

37. The allegations in Paragraph 37 are not directed to this Defendant so no response is required. To the extent one is deemed required, Defendant denies the allegations in Paragraph 37 for lack of knowledge or information sufficient to form a belief about the truth of these allegations.

38. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 38.

Breach of Warranty

39. The allegations in Paragraph 39 are not directed to this Defendant so no response is required. To the extent one is deemed required, Defendant denies the allegations in Paragraph 39 for lack of knowledge or information sufficient to form a belief about the truth of these allegations.

40. The allegations in Paragraph 40 are not directed to this Defendant so no response is required. To the extent one is deemed required, Defendant denies the allegations in Paragraph 40 for lack of knowledge or information sufficient to form a belief about the truth of these allegations.

41. The allegations in Paragraph 41 are not directed to this Defendant so no response is required. To the extent one is deemed required, Defendant denies the allegations in Paragraph 41 for lack of knowledge or information sufficient to form a belief about the truth of these allegations.

42. The allegations in Paragraph 42 are not directed to this Defendant so no response is required. To the extent one is deemed required, Defendant denies the allegations in Paragraph

42 for lack of knowledge or information sufficient to form a belief about the truth of these allegations.

Negligence Per Se

43. The allegations in Paragraph 43 are not directed to this Defendant so no response is required. To the extent one is deemed required, Defendant denies the allegations in Paragraph 43 for lack of knowledge or information sufficient to form a belief about the truth of these allegations.

44. The allegations in Paragraph 44 are not directed to this Defendant so no response is required. To the extent one is deemed required, Defendant denies the allegations in Paragraph 44 for lack of knowledge or information sufficient to form a belief about the truth of these allegations.

45. The allegations in Paragraph 45 are not directed to this Defendant so no response is required. To the extent one is deemed required, Defendant denies the allegations in Paragraph 45 for lack of knowledge or information sufficient to form a belief about the truth of these allegations.

46. The allegations in Paragraph 46 are not directed to this Defendant so no response is required. To the extent one is deemed required, Defendant denies the allegations in Paragraph 46 for lack of knowledge or information sufficient to form a belief about the truth of these allegations.

47. The allegations in Paragraph 47 are not directed to this Defendant so no response is required. To the extent one is deemed required, Defendant denies the allegations in Paragraph 47 for lack of knowledge or information sufficient to form a belief about the truth of these allegations.

Negligence

48. The allegations in Paragraph 48 are not directed to this Defendant so no response is required. To the extent one is deemed required, Defendant denies the allegations in Paragraph 48 for lack of knowledge or information sufficient to form a belief about the truth of these allegations.

49. The allegations in Paragraph 49 are not directed to this Defendant so no response is required. To the extent one is deemed required, Defendant denies the allegations in Paragraph 49 for lack of knowledge or information sufficient to form a belief about the truth of these allegations.

50. Defendant denies the allegations against it in Paragraph 50 and lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 50 as to the other Defendants.

51. The allegations in Paragraph 51 are not directed to this Defendant so no response is required. To the extent one is deemed required, Defendant denies the allegations in Paragraph 51 for lack of knowledge or information sufficient to form a belief about the truth of these allegations.

Liability Imputed To All Defendants

52. Defendant admits that it has common ownership and shares certain business services with Defendant NECC. Defendant denies the remaining allegations against it in Paragraph 52 and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.

53. Defendant denies the allegations against it in Paragraph 53.

54. Defendant is not required to respond to the allegations in Paragraph 54 that set forth legal conclusions. However, to the extent that such allegations may be construed against it, Defendant denies them and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.

DAMAGES

Compensatory

55. Defendant is not required to respond to the allegations in Paragraph 55 that set forth legal conclusions. However, to the extent that such allegations may be construed against it, Defendant denies them and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.

56. Defendant is not required to respond to the allegations in Paragraph 56 that set forth legal conclusions. However, to the extent that such allegations may be construed against it, Defendant denies them and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.

Punitive

57. Defendant denies the allegations against it in Paragraph 57 and further denies that Plaintiffs are entitled to recover punitive damages. Defendant is not required to respond to the allegations in Paragraph 57 that are not directed to it. To the extent one is deemed required, Defendant denies the allegations in Paragraph 57 for lack of knowledge or information sufficient to form a belief about the truth of these allegations.

RESPONDING TO WHEREFORE CLAUSE

Defendant denies entitlement to the relief requested in the Complaint. Defendant demands a trial by jury.

DEFENSES AND AFFIRMATIVE DEFENSES

During the course of litigation, a number of defenses and/or affirmative defenses may become available to Defendant. To the extent any of the following are available and may apply, notice is hereby given of the following:

1. The Complaint fails to state a claim or cause of action cognizable in law or equity against Defendant Ameridose.
2. The Complaint fails to allege a cognizable claim for breach of any applicable standard for the practice of pharmacy as to Defendant Ameridose.
3. Plaintiffs lack standing to sue Defendant Ameridose.
4. Defendant did not make the product in question and has no liability here since it is a separate entity not responsible for the acts of the other Defendants.
5. The allegations of the Complaint do not adequately set forth the elements required to overcome the presumption of corporate separateness under applicable state law.
6. The Complaint fails to sufficiently identify a preparation compounded or manufactured by this Defendant.
7. The Defendant further states that if the Plaintiffs underwent the medical procedure, they did so after having been fully, fairly, and reasonably informed and made aware of risks and uncertainties involved, and that after having been so informed consistent with the informed consent doctrine of Tennessee, they exercised their informed consent to the performance of the procedure.
8. The alleged injuries or damages may have been proximately caused by one or more unforeseeable, independent intervening or superseding events beyond the control of and

unrelated to the conduct of Defendant, including Plaintiff's comparative fault, pre-existing medical condition, and/or idiosyncratic reaction.

9. Adequate warnings and information were available to the medical profession, including any prescribing or administering healthcare provider.

10. Defendant relies upon all applicable defenses afforded it under the Tennessee Product Liability Act of 1978, Tenn. Code Ann. § 29-28-101, *et seq.*

11. To the extent that Plaintiffs' claims are based on violations of the Federal Food Drug & Cosmetic Act, such claims must fail since there is no private right of action regarding these alleged violations.

12. Defendant denies that any injuries or damages claimed by Plaintiffs were the direct and proximate result of any negligence or other conduct on its part. Defendant further avers that any recovery to which Plaintiffs may be entitled is barred or reduced by the negligence or acts of third parties or other responsible entities under the doctrine of comparative fault and that Defendant is responsible for only that portion of fault properly allocated to Defendant, which it denies. Although liability is denied, and without conceding or alleging that any co-defendant in this action is liable to Plaintiffs under any theory, pleading in the alternative only and incorporating by reference the allegations in the Complaint as to the co-defendants, Defendant gives notice of its possible intent to rely on the doctrine of comparative fault based on the potential fault of Plaintiffs, co-defendants, and/or other non-parties to reduce and/or bar Plaintiffs' recovery against Defendant at trial.

13. Plaintiffs are not entitled to recover exemplary or punitive damages in this case because such damages would result in violations of the United States Constitution, the Tennessee Constitution, and applicable federal and state law.

WHEREFORE, Defendant demands Judgment of this Court:

- a. dismissing the Complaint against it, with prejudice;
- b. awarding to Defendant the costs, expenses, and fees associated with defending this action; and
- c. granting such other and further relief, both legal and equitable, that the Court deems just and proper.

Dated: December 21, 2012

Respectfully submitted,

/s/ James A. Beakes III

James A. Beakes III, BPR# 24073

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Attorneys for Defendant Ameridose, LLC

CERTIFICATE OF SERVICE

This is to certify that a copy of the foregoing has been filed with the Clerk of the Court on December 21, 2012 using the ECF system that sent notification of this filing to all ECF-registered counsel of record via e-mail generated by the Court's ECF system.

/s/ James A. Beakes III

Attorney for Defendant Ameridose, LLC